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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/576,839	04/20/2006	Roger Alberto	1621 WO/US	2298
Jerad Seurer Mallinckrodt Inc. 675 McDonnell Boulevard P.O. Box 5840 St. Louis, MO 63134				
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EXAMINER				
JONES, DAMERON LEVEST				
ART UNIT		PAPER NUMBER		
1618				
MAIL DATE		DELIVERY MODE		
09/18/2009		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/576,839

**Applicant(s)**

ALBERTO ET AL.

**Examiner**

D L. Jones

**Art Unit**

1618

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 08 September 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 34, 37-49 and 51-53 is/are pending in the application.
- 4a) Of the above claim(s) 37-44 and 46 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 51-53 is/are allowed.
- 6) ☒ Claim(s) 34, 45, and 47-49 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
- Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **ACKNOWLEDGMENTS**

1. The Examiner acknowledges receipt of the amendment filed 9/8/09 wherein claims 1-33, 35, 36, and 50 were canceled and claims 45 and 51 were amended. In addition, the Examiner acknowledges receipt of the request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/8/09 has been entered.

**Note:** Claims 34, 37-49, and 51-53 are pending.

## **RESPONSE TO APPLICANT'S AMENDMENT ARGUMENTS**

2. The Applicant's arguments and/or amendment filed 9/8/09 to the rejection of claims 34, 45, 46, 49, and 50 made by the Examiner under 35 USC 102 and/or 112 have been fully considered and deemed persuasive-in-part for the reasons set forth below.

### **112 Second Paragraph Rejections**

I. The 112, second paragraph rejection over claims 45 and 50 are WITHDRAWN because Applicant has amended/canceled the claim to overcome the rejections.

II. The 112 second paragraph rejection over claim 46 is WITHDRAWN for reasons of record in Applicant's response.

**102 Rejection**

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. The rejection of claims 34 and 49 under 35 U.S.C. 102(b) as being anticipated by Dyszlewski et al (Molecular Imaging, January 2002, Vol. 1, pages 24-35) is MAINTAINED for reasons of record in the office action mailed 6/5/09 and those set forth below.

In summary, Applicant asserts that the compound in Dyszlewski et al does not encompass the instant invention because the cited prior art discloses nitrile substituents, not isocyanide substituents as set forth in the instant invention. Applicant asserts that the Examiner has improperly interpreted the term 'isonitrile' and 'isocyanide'. In addition, Applicant pointed out that the Examiner used Wikipedia in defining the terms 'isocyanide' and 'isonitrile'. Applicant stated that according to the Commissioner for Patents and his comments in the September 4, 2006 issue of Business Week, Wikipedia is a source that is constantly changing; thus, it is not on the list of acceptable sources. Applicant submitted a copy of the September 4, 2006 Business Week issue for the Examiner's review.

Applicant's arguments are non-persuasive for the reasons of record in the office action mailed 6/5/09 and those set forth below. First, since Wikipedia is not an 'acceptable' source, definitions for the terms 'isonitrile', 'isocyanide', and 'carbylamine'

are attached. The definitions are from Hawley's Condensed Chemical Dictionary, 14<sup>th</sup> Edition (© 2002) by John Wiley & Sons, Inc. Specifically, the definitions are being made of record to illustrate that the terms 'isocyanide' and 'isonitrile' may be used interchangeably (see definitions below).

isonitrile

**isonitrile**  
See carbylamine.

Hawley's Condensed Chemical Dictionary, 14th Edition  
Copyright ©2002 by John Wiley & Sons, Inc.

isonitrile

**isonitrile**  
See carbylamine.

Hawley's Condensed Chemical Dictionary, 14th Edition  
Copyright ©2002 by John Wiley & Sons, Inc.

carbylamine

**carbylamine**  
isocyanide; isonitrile  
 $\text{N}=\text{C}-\text{C}_6\text{H}_5$   
An unpleasantly odored compound containing the radical  $\text{N}=\text{C}$ .

Hawley's Condensed Chemical Dictionary, 14th Edition  
Copyright ©2002 by John Wiley & Sons, Inc.

Thus, based on definitions set forth in the art, it is the Examiner's position that while the cited prior art may refer to its compound as an isonitrile, the definitions of the terms illustrate that a compound is an isocyanide structure may be referred to as an isonitrile. Hence, the rejection is deemed proper.

**WITHDRAWN CLAIMS**

5. Claims 37-44 and 46 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention/species.

**NEW GROUNDS OF REJECTIONS**

**112 First Paragraph Rejections (Written Description)**

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 34, 45, and 47-49 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention..

Applicant is reminded that an Inventor is entitled to a patent to protect his work only if he/she produces or has possession of something truly new and novel. The invention being claimed must be sufficiently concrete so that it can be described for the world to appreciate the specific nature of the work that sets it apart from what was before. The Inventor must be able to describe the item to be patented with such clarity that the Reader is assured that the Inventor actually has possession and knowledge of the unique composition that makes it worthy of patent protection. The instant application does not sufficiently describe the invention as it relates to the other definitions for the variables X1, X2, and X3 when only two of the variables are selected

from the group consisting of CO, NH<sub>3</sub>, aromatic heterocycles, thioethers, and isocyanides.. What the Reader gathers from the instant application is a desire/plan/first step for obtaining a desired result. While the Reader can certainly appreciate the desire for achieving a certain end result, establishing goals does not necessarily mean that an invention has been adequately described.

While compliance with the written description requirements must be determined on a case-by-case basis, the real issue here is simply whether an adequate description is necessary to practice an invention described only in terms of its function and/or based on a disclosure wherein a description of the components necessary in order for the invention to function are lacking. In order to satisfy the written description requirement, the specification must describe every element of the claimed invention in sufficient detail so that one of ordinary skill in the art would recognize that the Inventor possessed the claimed invention at the time of filing. In other words, the specification should describe an invention and does so in sufficient detail that one skilled in the art can clearly conclude that the Inventor created what is the claimed. Thus, the written description requirement is lacking in the instant invention since the various terms as set forth above are not described in a manner to clearly allow persons of ordinary skill in the art to recognize that Applicant invented what is being claimed.

**112 First Paragraph Rejections (Scope of Enablement)**

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 34, 45, and 47-49 are rejected under 35 U.S.C. 112, first paragraph, , because the specification, while being enabling for X1, X2, and X3 wherein two are CO, NH3, aromatic heterocycles, thioethers, and isocyanides does not reasonably provide enablement for the third variable in the X1, X2, and X3 grouping when only two variables are CO, NH3, aromatic heterocycles, thioethers, and isocyanides. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

There are several guidelines when determining if the specification of an application allows the skilled artisan to practice the invention without undue experimentation. The factors to be considered in determining what constitutes undue experimentation were affirmed by the court in *In re Wands* (8 USPQ2d 1400 (CAFC 1986)). These factors are (1) nature of the invention; (2) state of the prior art; (3) level of one of ordinary skill in the art; (4) level of predictability in the art; (5) amount of direction and guidance provided by the inventor; (6) existence of working examples; (7) breadth of claims; and (8) quantity of experimentation needed to make or use the invention based on the content of the disclosure.

(1) Nature of the invention

The claims are directed to a method of treating cancer by administering a metal tricarbonyl compound to a subject.

(2) State of the Prior Art



The state of the prior art is such that it a single group of compounds will not treat all cancers given the great diversity between various types of cancers. The unpredictability of cancers and its response to certain compounds not only varies from person to person, but varies as to the type of cancer being treated. As a result, there is a considerable amount of testing that is required .

(3) Level of one of ordinary skill in the art

The level of one of ordinary skill in the art is high. Independent claim 34 encompasses a vast number of possible values for the variables X1, X2, and X3. In addition, independent claim 34 is directed to all cancers. Applicant's specification does not enable the public to make or use such a vast number compounds useful for treating cancer.

(4) Level of predictability in the art

The art pertaining to compounds for treating cancer is highly unpredictable. Determining the various types and classes of cancers that will respond to various compounds requires various experimental procedures and without guidance that is applicable to all cancers, there would be little predictability in performing the claimed invention. Hence, there is little predictability in performing the claimed invention, absent some guidance, since not all cancers respond to the same compounds.

(5) Amount of direction and guidance provided by the inventor

Independent claim 34 encompasses a vast number of cancers and compounds. Applicant's limited guidance does not enable the public to prepare such a numerous amount of compounds for treating all types of cancers. There is no directional guidance

for the compounds and specific cancers that are treatable. Hence, there is no enablement for all possible compounds and treatment of all types of cancers.

(6) Breadth of claims

The claims are extremely broad due to the vast number of possible compounds and types of cancers known to exist.

(7) Quantity of experimentation needed to make or use the invention based on the content of the disclosure

The specification does not enable any person skilled in the art to which it pertains to make or use the invention commensurate in scope with the claims. In particular, the specification fails to enable the skilled artisan to practice the invention without undue experimentation. Furthermore, based on the unpredictable nature of the invention, the state of the prior art, and the extreme breadth of the claims, one skilled in the art could not perform the claimed invention without undue experimentation.

**112 Second Paragraph Rejections**

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 34, 45, and 47-49 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims as written are ambiguous because in independent claim 34, the phrase 'at least two of X1, =X2, and X3 are monodentate ligands selected from the group consisting of CO, NH<sub>3</sub>, aromatic heterocycles, thioethers, and isocyanides'. In

particular, it is unclear what values of the remaining variable from the X1, X2, and X3 grouping Applicant is claiming that is compatible with the instant invention. Since claims 45 and 47-49 depend on claim 34 which is vague and indefinite, then dependent claims are also vague and indefinite.

#### **ALLOWABLE CLAIMS**

12. Claims 51-53 are allowable over the prior art of record for reasons of record in the office action mailed 6/5/09.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D L. Jones whose telephone number is (571)272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

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USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/D L. Jones/  
Primary Examiner  
Art Unit 1618

September 16, 2009